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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: John P. Atkinson, et al.

Serial No.: 08/126,505

Group Art Unit: 1812
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Filed: September 24, 1993

Examiner: Walsh, S.

For: MODIFIED TRUNCATED COMPLEMENT SYSTEM REGULATORS

Assistant Commissioner
for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §1.56, Applicants cite the following publications, copies of which are enclosed. The publications marked with an asterisk are unavailable at the present time. Copies will be provided as soon as they become available. Also enclosed are Forms PTO-1449 listing the publications cited in the present case and the publications cited in the parent applications, U.S. Serial No. 07/695,514 and U.S. Serial No. 08/210,266, and a copy of the International Search Report issued in International Application Number PCT/US94/10820, the PCT application corresponding to the above-identified patent application mailed on January 9, 1995. Pursuant to 37 C.F.R. §1.98(d), copies of the publications listed on the Forms PTO-1449 cited in U.S. Serial No. 07/695,514 and U.S. Serial No. 08/210,266 are not provided herewith. However, copies of these documents will be made available to the Examiner upon request. Also enclosed is a check in the amount of \$220.00,

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U.S.S.N. 08/126,505
Filed: September 24, 1993
INFORMATION DISCLOSURE STATEMENT

the fee for consideration of this Information Disclosure Statement.

Applicants request that all of the publications identified on the enclosed Forms PTO-1449 be made of record in the above-identified application, whether or not they are included in the following list.

U.S. Patent

<u>Number</u>	<u>Issue Date</u>	<u>Patentee</u>
4,883,784	11/28/89	Kaneko

Foreign Documents

<u>Number</u>	<u>Publication Date</u>	<u>Country</u>
WO 89/01041	02/09/89	PCT

Publications

Adams, et al., "Contribution of the Repeating Domains of Membrane Cofactor Protein (CD46) of the Complement System to Ligand Binding and Cofactor Activity," J. Immunology 147:3005-3011 (1991)

Alsenz, et al., "Localization of the complement-component-C3b-binding site and the cofactor activity for factor I in the 38kDa tryptic fragment of factor H," Biochem. J. 389 (1984)

Atkinson and Farries, "Separation of self from non-self in the complement system," Immun. Today 8:212 (1987)

Ballard, et al., "A Polymorphism of the Complement Regulatory Protein MCP (Membrane Cofactor Protein or gp45-70)¹ J. of Immun. 138:3850-3855 (1987)

U.S.S.N. 08/126,505

Filed: September 24, 1993

INFORMATION DISCLOSURE STATEMENT

Ballard, et al., "Biochemical Characterization of Membrane Cofactor Protein of the Complement System," J. of Immun. 141:3923-3929 (1988)

Birmingham and Cosio, "Characterization of the Baboon Erythrocyte C3b-Binding Protein," J. of Immun. 142:3140-3144 (1989)

Birmingham, et al., "Primary Sequence of an Alternatively Spliced Form of CR1," J. of Immunol. 691 (1994)

Bora, et al., "Structural Gene for Human Membrane Cofactor Protein (MCP) of Complement Maps to Within 100 kb of the 3' End of the C3b/C4b Receptor Gene," J. Exp. Med. 169:597-602 (1989)

Brauer, et al., "Use of C6-Deficient Rats to Evaluate the Mechanism of Hyperacute Rejection of Discordant Cardiac Xenografts," J. of Immunol. 151:7240-7248 (1993)

Capechi, (1989)*

Caras, et al., "Signal for Attachment of a Phospholipid Membrane Anchor in Decay Accelerating Factor," Science 238:1280 (1987)

Caras, I.W., et al., "Cloning of decay-accelerating factor suggests novel use of splicing to generate two proteins," Nature (1987) 325:545

Carel, et al., "Structural Requirements for C3d,g/Epstein-Barr Virus Receptor (CR2)/CD21 Ligand Binding, Internalization and Viral Infection," J. Biol. Chem. 265:12293-12299 (1990)

Chung, L.P, et al., "Molecular cloning and characterization of the cDNA coding for C4b-binding protein, a regulatory protein of the classical pathway of the human complement system," Biochem. J. 230:133 (1985)

Clemenza, et al., "Generation of a Functional Domain of CR1 with Increased Ligand Binding and Cofactor Activities,"*

Cole, J.L., et al., "Identification of an additional class of C3-binding membrane proteins of human peripheral blood

U.S.S.N. 08/126,505
Filed: September 24, 1993
INFORMATION DISCLOSURE STATEMENT

leukocytes and cell lines," Proc. Natl. Acad. Sci. USA 82:859-863 (1985)

Coyne, et al., "Mapping of Epitopes, Glycosylation Sites, and Complement Regulatory Domains in Human Decay Accelerating Factor," J. Immunology 149:2906-2913 (1992)

Dykman, et al., "Polymorphism of human erythrocyte C3b/C4b receptor," Proc. Natl. Acad. Sci. USA 80:1698-1702 (1983)

Dykman, et al., "Structural Heterogeneity of the C3b/C4b Receptor (CR1) on Human Peripheral Blood Cells," J. Exp. Med. 157:2160-2165 (1983)

Farries, et al., "Competition for Binding Sites on C3b by CR1, CR2, MCP, Factor B and Factor H," Complement Inflamm 7:30-41 (1990)

Fodor, et al., "A Novel Bifunctional Chimeric Complement Inhibitor That Regulates C3 Convertase and Formation of the Membrane Attack Complex," J. of Immunol. 4135-4138 (1995)

Ghebrehiwet, B., et al., "Purification and Immunochemical Characterization of Soluble Forms of the Two Types of C1Q Receptors," Complement and Complement Receptors Abstract 2751 (1994)

Goujet-Zalc, et al., "Marmoset Red Blood Cell Receptor for Membrane-Associated Complement Components Is Not Related to Human CR1: Partial Characterization of the C3-Binding Proteins Responsible for the Spontaneous Rosette Formation between Marmoset Red Blood Cells and Human Leukocytes," Cell. Immun. 109:282-294 (1987)

Hillarp, A., and Dahlback, B., "Cloning of cDNA coding for the β chain of human complement component C4b-binding protein: Sequence homology with the α chain," Proc. Natl. Acad. Sci. USA 87:1183 (1990)

Himmelfarb, et al., "Soluble complement receptor 1 inhibits both complement and granulocyte activation during ex vivo hemodialysis," J. Lab. Clin. Med. 126:392-400 (1995)

Hogg, N., et al., "Identification of an anti-monocyte monoclonal antibody that is specific for membrane complement receptor type one (CR₁)," Eur. J. Immunol. 14:236-243 (1984)

U.S.S.N. 08/126,505

Filed: September 24, 1993

INFORMATION DISCLOSURE STATEMENT

Holers, et al., "Human C3b- and C4b-regulator proteins: a new multi-gene family," Immun. Today 6:188 (1985)

Hourcade, et al., "Duplication and Divergence of the Amin-terminal Coding Region of the Complement Receptor 1 (CR1) Gene," J. of Biol. Chem. 265:974-980 (1990)

Hourcade, D., et al., "Analysis of the Human Regulators of Complement Activation (RCA) Gene Cluster with Yeast Artificial Chromosomes (YACs)." Genomics 12:289-300 (1992)

Hourcade and Atkinson, "The Regulators of Complement Activation (RCA) Gene Cluster," Progress in Immun. VII:171 (1989)

Janatova, et al., "Disulfide Bonds Are Localized within the Short Consensus Repeat Units of Complement Regulatory Proteins: C4b-Binding Protein," Biochem. 28:4754-4761 (1989)

Joyner et al., "Production of a mutation in mouse *En-2* gene by homologous recombination in embryonic stem cells," Nature 338:153-156 (1989)

Kalli, et al., "Interaction of iC3b with Recombinant Isotypic and Chimeric Forms of CR2," J. Immunology 147:590-594 (1991)

Kalli, et al., "Mapping of the C3b-binding Site of CR1 and Construction of a (CR1)₂-F(ab')₂ Chimeric Complement Inhibitor," J. Exp. Med. 174:1451-1460 (1991)

Kim, "Isolation and Identification of Trophoblast Lymphocyte Cross-reactive (TLX) Antigens from Human Lymphocytes," J. of Biol. Chem. 264:9780-9784 (1989)

Klickstein, L.B., et al., "Human C3b/C4b Receptor (CR1)," J. Exp. Med. 165:1095 (1987)

Krych, et al., "Sites within the complement C3b/C4b receptor important for the specificity of ligand binding," Proc. Natl. Acad. Sci. USA 88:4353-4357 (1991)

Krych, et al., "Identification of a C3b Binding Domain of Human Complement C3b/C4b Receptor (CR1)," FASEB J. 4(7) (1990)

U.S.S.N. 08/126,505
Filed: September 24, 1993
INFORMATION DISCLOSURE STATEMENT

Kunkel, T.A., et al., "Rapid and Efficient Site-Specific Mutagenesis without Phenotypic Selection," Methods Enzymol 154:367-382 (1987)

Liszewski, M. Kathryn, et al., "Control of the Complement System," Adv. in Immunol. In Press

Lovell-Badge, "Introduction of DNA into embryonic stem cells," Teratocarcinomas and embryonic stem cells, a practical approach, 153 (ed. E.J. Robertson, IRL Press, 1987)

Lublin, et al., "The Gene Encoding Decay-Accelerating Factor (DAF) is Located in the Complement-Regulatory Locus on the Long Arm of Chromosome," J. Exp. Med. 165:1731-1736 (1987)

Lublin, D.M., et al., "Molecular Cloning and Chromosomal Localization of Human Membrane Cofactor Protein (MCP)," J. Exp. Med. 168:181 (1988)

Lublin and Atkinson, "Decay-Accelerating Factor: Biochemistry, Molecular Biology, and Function," Ann. Rev. Immunol. 7:35-58 (1989)

Lublin and Atkinson, "Decay-Accelerating Factor and Membrane Cofactor Protein," Curr. Topics in Micro. and Immun. 153:123 (1989)

Makrides, S.C., et al., "Cell Surface Expression of the C3b/C4b Receptor (CR1) Protects Chinese Hamster Ovary Cells from Lysis by Human Complement," J. Biol. Chem. 267:24754-24761 (1992)

McNearney, et al., "Membrane Cofactor Protein of Complement is Present on Human Fibroblast, Epithelial, and Endothelial Cells," J. Clin. Invest. 84 (1989)

Medof, M.E., et al., "Cloning and characterization of cDNAs encoding the complete sequence of decay-accelerating factor of human complement," Proc. Natl. Acad. Sci. USA (1987) 84:2007

Moore, "CRRP: A Guinea Pig Protein, Identified by Sequence Homology to Human CR1, Which Contains Two Short Consensus Repeat Motifs and Appears Not To Be Transmembrane or Secreted," J. of Immunol. 147:3615-3622 (1991)

Moore, M.D., et al., "Molecular cloning of the cDNA encoding the Epstein-Barr virus/C3d Receptor (complement receptor

U.S.S.N. 08/126,505
Filed: September 24, 1993
INFORMATION DISCLOSURE STATEMENT

type 2), of human B lymphocytes," Proc. Natl. Acad. Sci. USA 84:9194 (1987)

Nickells, et al., "Identification of Complement Receptor Type 1-Related Proteins on Primate Erythrocytes," J. of Immunol. 2829 (1995)

Nickells, et al., "Identification of 65-70kDa CR1 Molecules from Primate E," Complement and Complement Receptors FASEB Journal Abstract 2749, (1994)

O'Shea, J.J., et al., "Evidence for Distinct Intracellular Pools of Receptors for C3b and C3bi in Human Neutrophils," J. Immunol. 134:2580-2587 (1985)

Ogata, et al., "Murine C4b-Binding Protein," J. Immunology 150:2273-2280 (1993)

Post, et al., "Membrane Cofactor Protein of the Complement System: Alternative Splicing of Serine/Threonin/Proline-rich Exons and Cytoplasmic Tails Produces Multiple Isoforms that Correlate with Protein Phenotype," J. Exp. Med. 174:93-102 (1991)

Potter, et al., "Enhancer-dependent expression of human K immunoglobulin genes introduced into mouse pre-B lymphocytes by electroporation," Proc. Natl. Acad. Sci. USA 81:161 (1984)

Pruitt, et al., "The Effect of Soluble Complement Receptor Type 1 on Hyperacute Xenograft Rejection," Transplantation 52:868-873 (1991)

Purcell, et al., "The human cell-surface glycoproteins HuLy-m5, membrane co-factor protein (MCP) of the complement system, and trophoblast leucocyte-common (TLX) antigen, are CD46," Immun. 70:155-161 (1990)

Remington: *The Science and Practice of Pharmacy* Nineteenth Edition, Volumes I and II

Ripoche, J., et al., "The complete amino acid sequence of human complement factor H," Biochem. J. 249:593 (1988)

Seya, T., et al., "Purification and Functional Analysis of the Polymorphic Variants of the C3b/C4b Receptor (CR1) and

U.S.S.N. 08/126,505

Filed: September 24, 1993

INFORMATION DISCLOSURE STATEMENT

Comparison with H, C4b-Binding Protein (C4bp), and Decay Acceleration Factor (DAF)," J. Immunology 135:2661 (1985)

Seya and Atkinson, "Functional properties of membrane cofactor protein of complement," Biochem. J. 264:581 (1989)

Seya, et al., "Membrane Cofactor Protein (MCP or gp 45-70): A Distinct Complement Regulatory Protein with a Wide Tissue Distribution,"*

Seya, et al., "Distribution of membrane cofactor protein of complement on human peripheral blood cells. An altered form is found on granulocytes," Eur. J. Immunol. 18:1289-1294 (1988)

Seya, et al., "Purification and Characterization of a Membrane Protein (gp45-70) that is a Cofactor for Cleavage of C3b and C4b," J. Exp. Med. 163:837 (1986)

Seya, "membrane cofactor protein (MCP)," Complement Regulation (1988)

Southern and Berg, "Transformation of Mammalian Cells to Antibiotic Resistance with a Bacterial Gene Under Control of the SV40 Early Region Promoter," J. Mol. Appl. Gen. 1:327-341 (1982)

Stafford, et al., "Normal polymorphic variations and transcription of the decay accelerating factor gene in paroxysmal nocturnal hemoglobinuria cells," Proc. Natl. Acad. Sci. USA 85:880-884 (1988)

Subramanian, V., et al., "Ligand Binding by Chimpanzee Erythrocyte Complement Receptor," Complement and Complement Receptors, FASEB Journal Abstract 4447 (1994)

Weiss, J.J., et al., "Structure of the Human B Lymphocyte Receptor for C3d and the Epstein-Barr Virus and Relatedness to Other Members of the Family of C3/C4 Binding Proteins," J. Exp. Med. 167:1047 (1988)

Wong and Fearon, "p65: A C3b-Binding Protein on Murine Cells that Shares Antigenic Determinants with the Human C3b Receptor (CR1) and is Distinct from Murine C3b Receptor," J. of Immun. 134:4048 (1985)

U.S.S.N. 08/126,505
Filed: September 24, 1993
INFORMATION DISCLOSURE STATEMENT

Wong, "Structural and Functional Correlation of the Human Complement Receptor Type 1," J. of Investigative Dermatology 94:64S-67S (1990)

Wong, et al., "Identification of a partial cDNA clone for the human receptor for complement fragments C3b/C4b," Proc. Natl. Acad. Sci. USA 82:7711-7715 (1985)

Wong and Farrell, "Proposed Structure of the F' Allotype of Human CR1," J. of Immunol. 146:656-662 (1991)

Yu, et al., "Identification of a Third Component of Complement-binding Glycoprotein of Human Platelets," J. Clin. Invest. 78:494-501 (1986)

Zimmer and Gruss, "Production of chimaeric mice containing embryonic stem (ES) cells carrying a homoeobox Hox 1.1 allele mutated by homologous recombination," Nature 338:150-153 (1989)

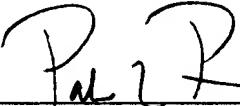
Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either

U.S.S.N. 08/126,505
Filed: September 24, 1993
INFORMATION DISCLOSURE STATEMENT

alone or in combination.

Respectfully submitted,



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